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INVESTOR IN PEOPLE

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Signed

Dated 3 February 2005

"ents Form 1/77

Patents Act 1977
(Rule 16)

THE PATENT OFFICE
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- 9 DEC 2003
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10DEC03 E858511-7 D00318
P01/7700 0.00-0328558.2

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference — KJL/CT/P5367

2. Patent application number *(The Patent Office will fill this part in)* — 0328558.2 — - 9 DEC 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Zi Medical plc
Unit 4 St Asaph Business Park
St Asaph
Denbighshire
LL17 0LJ

8523862001

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — An improved feed mechanism for a syringe pump

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

ROYSTONS

Tower Building,
Water Street,
Liverpool. L3 1BA
Merseyside.

Patents ADP number *(if you know it)* — 1438001 ✓

6. Priority: Complete this section if you are declaring priority from one or more earlier patent applications, filed in the last 12 months.

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. Divisionals, etc: Complete this section only if this application is a divisional application or resulted from an entitlement dispute (see note f)

Number of earlier UK application	Date of filing *(day / month / year)*

8. Is a Patents Form 7/77 (Statement of inventorship and of right to grant of a patent) required in support of this request? — Yes

Answer YES if:

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.

Otherwise answer NO (See note d)

9. Accompanying documents: A patent application must include a description of the invention. Not counting duplicates, please enter the number of pages of each item accompanying this form:

Continuation sheets of this form	
Description	8
Claim(s)	- CF
Abstract	-
Drawing(s)	4+4

10. If you are also filing any of the following, state how many against each item.

Priority documents	-
Translations of priority documents	-
Statement of inventorship and right to grant of a patent (Patents Form 7/77)	-
Request for a preliminary examination and search (Patents Form 9/77)	-
Request for a substantive examination (Patents Form 10/77)	-
Any other documents (please specify)	-

11. I/We request the grant of a patent on the basis of this application.

Signature(s) ROYSTONS Date 08/12/03

12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom

Kate J. Lees - 0151-236 5147/1417

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered YES in part 8, a Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) Part 7 should only be completed when a divisional application is being made under section 15(4), or when an application is being made under section 8(3), 12(6) or 37(4) following an entitlement dispute. By completing part 7 you are requesting that this application takes the same filing date as an earlier UK application. If you want the new application to have the same priority date(s) as the earlier UK application, you should also complete part 6 with the priority details.

Title: An improved feed mechanism for a syringe pump.

DESCRIPTION

The present invention relates to an improved feed mechanism for a syringe driver or pump.

Syringe drivers or pumps are well known. They are small, lightweight, battery operated machines that are designed to administer subcutaneous infusions of a prescribed amount of medication over a given period. A syringe driver basically consists of the machine itself, a syringe containing the medicine to be administered which is attached to the machine and a thin piece of tubing attached to the syringe which has a needle at the end of it. Syringe drivers are often provided with both the machine and the syringe contained within a housing to increase the portability of the device.

The drive mechanism for driving the plunger through the syringe barrel to dispense medication generally consists of a motor, gears and a threaded shaft. The motor causes rotation of the threaded shaft which, via an actuator attached thereto, effects movement of the plunger. Once the required medication has been dispensed, it is necessary to manually reset the syringe driver by pulling back the actuator and syringe plunger to the required degree. Conventionally, this is achieved by the provision of two half nuts around the threaded shaft, the manual disengagement of

which enables the actuator to be moved back to the end of the shaft to allow the plunger to be reset. However, these nuts are subject to a large amount of wear and tear and thus require frequent replacement.

It is an object of the present invention to provide an improved feed mechanism for a syringe driver or pump that aims to overcome, or at least alleviate the abovementioned drawbacks.

Accordingly, the present invention provides a syringe driver assembly comprising driver means for imparting controlled translational movement to a syringe plunger, the driver means comprising a motor driven unthreaded shaft, an odd number of bearings mounted with respect to the shaft and an actuator linked to said bearings for contacting a head of the plunger, wherein alternate bearings are set at the same angle relative to the shaft and adjacent bearings are set at an opposing angle relative to the shaft to cause movement of the bearings along the shaft and thereby affect movement of the actuator.

Preferably the assembly is provided with three bearings, each having a bore through which the shaft extends. Preferably, each bearing is offset with respect to the shaft wherein the outer bearings are mounted at the same angle relative to the shaft and the inner bearing is mounted at an equal and opposite angle thereto. The bore of each bearing should preferably be larger than the outer circumference of the shaft to

result in each bearing being oversized with respect to the shaft, thereby creating clearance between the shaft and each bearing.

The bearings are preferably made of a hardened steel, such as stainless steel. More preferably, the angle of inclination of each bearing relative to the shaft is less than 5 degrees, preferably 2-3 degrees.

Alternatively, the inclined bearings may be symmetrically spaced in one plane perpendicular to the shaft axis, the outer races of the bearings making radial contact with the shaft. In this embodiment, each bearing is preferably sprung loaded with respect to the shaft.

It is preferable for the bearings to be housed within a carriage that is moveable with respect to the shaft. Preferably, the carriage is connected to the actuator that contacts the plunger head of the syringe. The carriage is preferably provided with guides. The carriage and actuator may form an integral component.

It is preferable for the assembly to provide an axial force of at least 10 Newtons, more preferably at least 15 Newtons.

The assembly may be provided with means for manually disengaging one or more of the bearings to enable the bearings and/or carriage to slide with respect to the shaft. Preferably, the middle bearing is spring loaded with respect to the shaft

whereby operation of the spring mechanism disengages the middle bearing from the shaft. Preferably, the carriage is provided with a means for operation of the spring.

Alternatively, the assembly may be provided with automatic means for reversing the direction of travel of the carriage and actuator. For example, means may be provided to reverse the angle of inclination of the bearings with respect to the shaft to cause the bearings to travel in the opposite direction without changing the direction of rotation of the shaft.

Preferably, means is provided to detect any backward pressure exerted on the syringe driver assembly. More preferably, detection of a backward pressure above a certain threshold results in stopping of the motor.

For a better understanding of the present invention and to show more clearly how it may be carried into effect, reference will now be made by way of example only to the accompanying drawings in which:-

Figure 1 is a schematic perspective view of the internal components of a syringe driver assembly according to one embodiment of the present invention;

Figure 2 is a perspective front view of a carriage and drive shaft for a syringe driver feed mechanism according to one embodiment of the present invention;

Figure 3 is perspective view of the housing and drive shaft of Figure 2 with one half of the housing removed to show the internal components thereof;

Figure 4 is a plan view of the housing and drive shaft of Figure 2 with half of the housing removed to show the internal components thereof;

Figure 5 is a cross-sectional view through the carriage of Figure 2; and

Figure 6 is a schematic diagram illustrating the mounting of the bearings relative to the driver shaft.

Referring to Figure 1 of the accompanying drawings, the internal components of a syringe driver are shown comprising a drive shaft 2 carrying a carriage 4 mounted on guides 5, the shaft being driven by a motor 6. It is to be appreciated that the components would be contained within a housing but this has been omitted from the drawings for the sake of simplicity. The carriage 4 is connected to an actuator 8 that abuts the plunger 10a of a syringe 10 when one is placed within the syringe driver assembly. Movement of the actuator causes displacement of the plunger thereby causing fluid to be dispensed from the nozzle 10b of the syringe, as required.

Conventionally, a threaded shaft is used to convert the rotary motion of the motor driven shaft into linear motion. However, in order to reset the shaft with the actuator in the desired position to dispense fluid from a syringe, two half-nuts are provided around the shaft that may be disengaged therefrom in order for the drive carriage to be moved back to its desired position. This is undesirable because the nuts are subject to a large amount of wear and tear, necessitating frequent replacement of the parts. The present invention provides an alternative feed mechanism for driving the plunger of the syringe that aims to overcome the abovementioned drawbacks.

Referring to Figures 1 to 5 of the accompanying drawings, the components of a feed mechanism for driving a syringe according to one embodiment of the present invention is illustrated. The syringe driver comprises a smooth, unthreaded shaft 2 or bar that is rotated by means of a motor 6. The shaft runs through a carriage 4 that is mounted on guides 5, the carriage containing three anti-friction bearings 26, 27, 28 that are offset with respect to the shaft. An actuator 8 is connected to the carriage 4 whereby movement of the carriage imparts movement to the actuator. The actuator abuts the syringe plunger of a syringe to affect movement thereof to result in fluid being dispensed from the syringe.

The rotary motion of the shaft is converted into linear motion by means of the three bearings 26, 27 and 28 that are fixed within the carriage. The three bearings are configured such as to provide clearance between each bearing and the shaft. The two outer bearings 26, 28 are fixed at the same angle relative to the longitudinal axis of the shaft and the middle bearing 27 is fixed at an equal and opposite angle with respect to the shaft, resulting in the outer bearings running on their corresponding edges with respect to the shaft with the middle bearing running on its opposing edge. This causes the bearings to "roll" along the length of the shaft thereby converting the rotary input R provided by the motor-driven shaft into a linear output T (see Figure 6). Thus, this arrangement enables the controlled feed of the carriage, and thus the actuator, in one direction only, by means of the rotary motion of the shaft. The actuator engages with the plunger of the syringe thereby enabling controlled discharge of fluid within the syringe.

The forces on the shaft are collectively externally balanced and the shaft is supported in a bearing system that fixes it on its axial and radial axes but allows low friction rotation. A stepping motor is preferably used to drive rotation of the shaft. The shaft and the bore of the bearings should be of hardened steel, such as stainless steel.

The abovementioned mechanism should be able to exert an axial force of at least 10 Newtons, preferably at least 15 Newtons on the syringe piston assembly since the largest syringe conventionally used (30ml) generally applies a backward force of around 15 Newtons. It has been found that the feed mechanism of the present invention can exert an axial force of 30 Newtons and accordingly, the mechanism is suitable for dispensing fluid from all standard sizes of syringe.

A feed rate of 0.5mm per revolution of the shaft is generally used and the shaft is in the order of 4.0mm in diameter. These parameters can be used to determine the required angle of inclination of the bearings with respect to the shaft using the following formula:

$$\theta = \mathrm{Tan}^{-1}\,(0.5/(4.00*\pi)) = 2.2785 \text{ degrees, say } 2.3 \text{ deg.}$$

The present invention also provides for the return of the carriage and actuator to their original positions to enable a new syringe to be inserted into the assembly. This is achieved by disengagement of the middle bearing 27 from the shaft by means

of a push spring mechanism 40 (see Figures 2 to 5) which enables the bearings to slide along the shaft, thereby allowing the carriage and actuator to be repositioned as desired.

Alternatively, the assembly may be provided with means for the automatic reversal of the carriage and actuator without changing the direction of rotation of the shaft. This may be achieved by providing means whereby the angle of inclination of the bearings relative to the shaft is reversed, i.e. the positioning of the bearings with respect to the shaft is altered to its corresponding mirror image.

The syringe driver assembly of the present invention is preferably provided with a mechanism for detection of an overload of the system, for example if an occlusion occurs in the line with results in a back pressure build up in the syringe, whereby detection of an overload causes the motor to stop.

In an alternative embodiment of the present invention, the three inclined bearings may be symmetrically spaced in one plane perpendicular to the shaft axis with the outer races of the bearings making radial contact with the shaft (not shown). In this configuration, the bearings may be spring loaded onto the shaft to control the contact force, removing the need for precision manufacture of the bearings to shaft location.

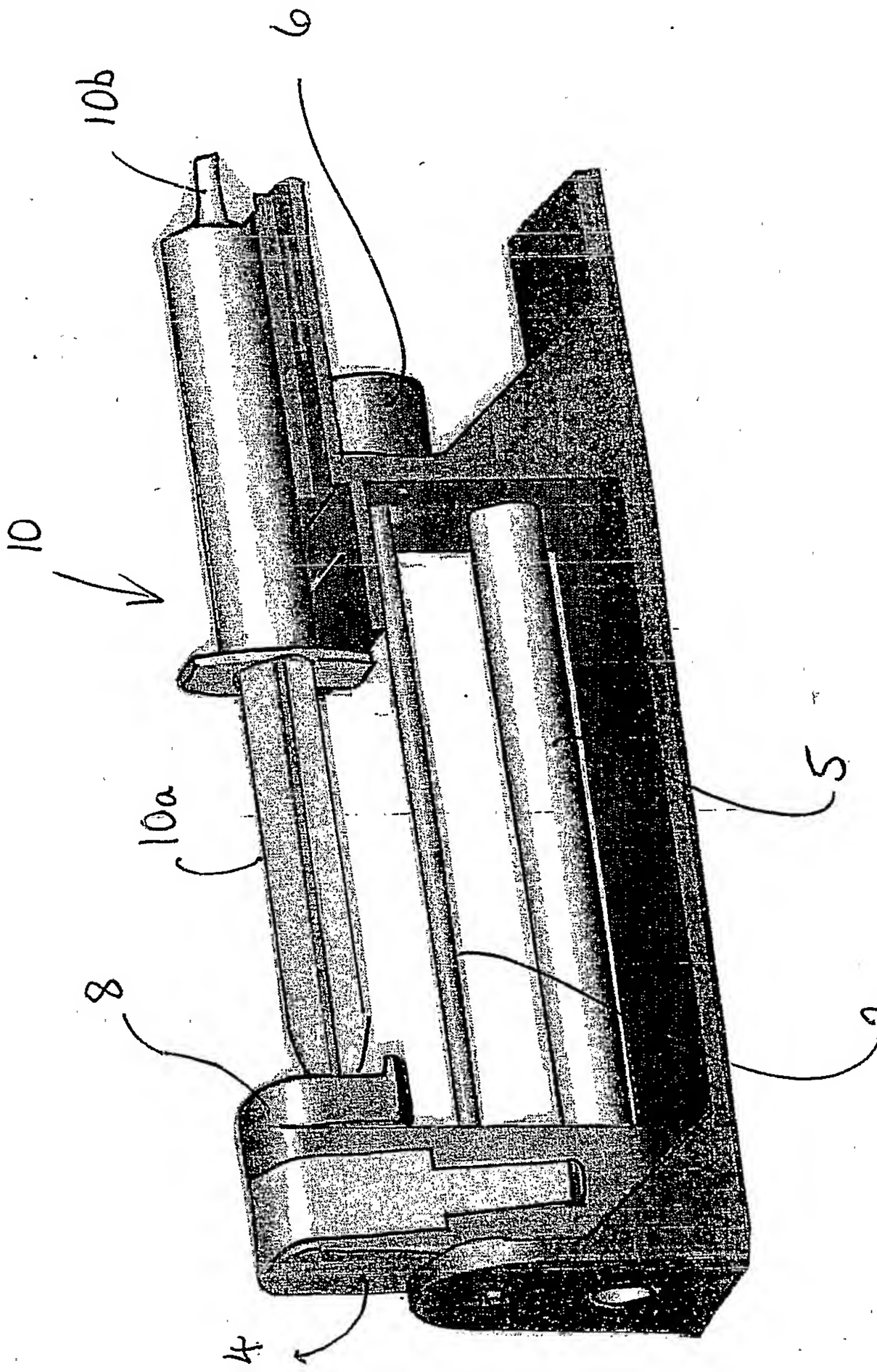

FIG. 1

FIG. 2.

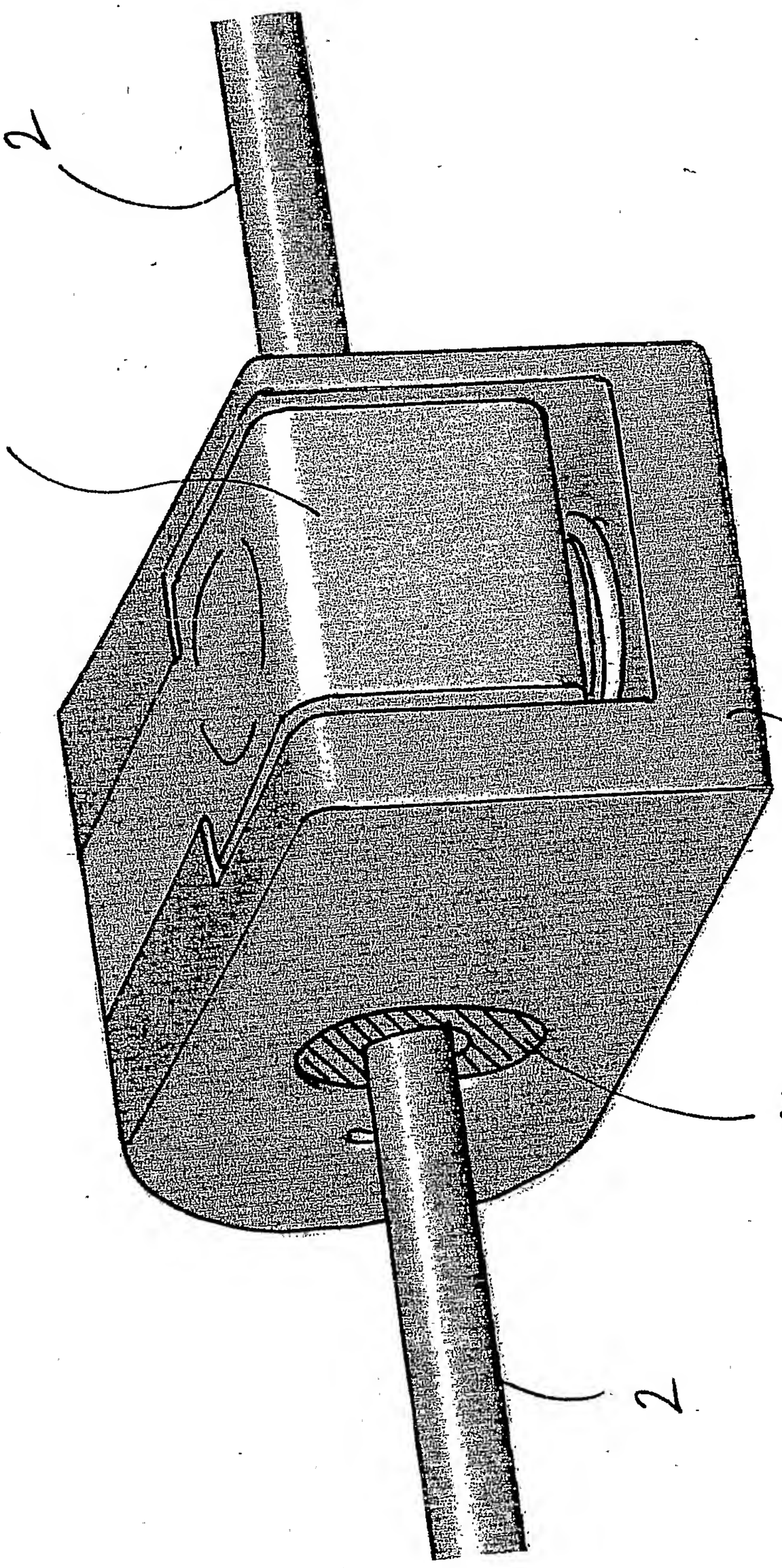

FIG.3

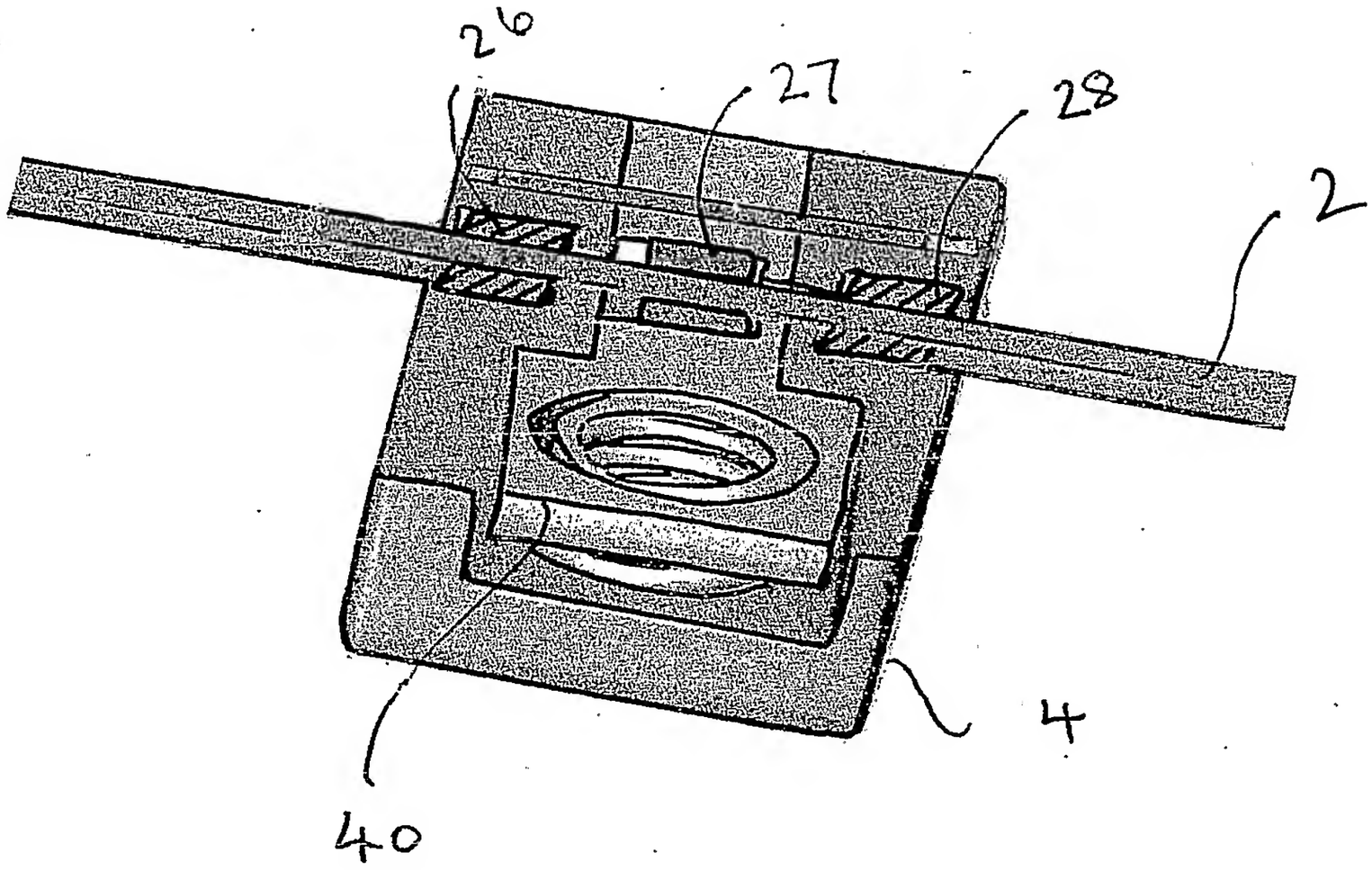

FIG.4

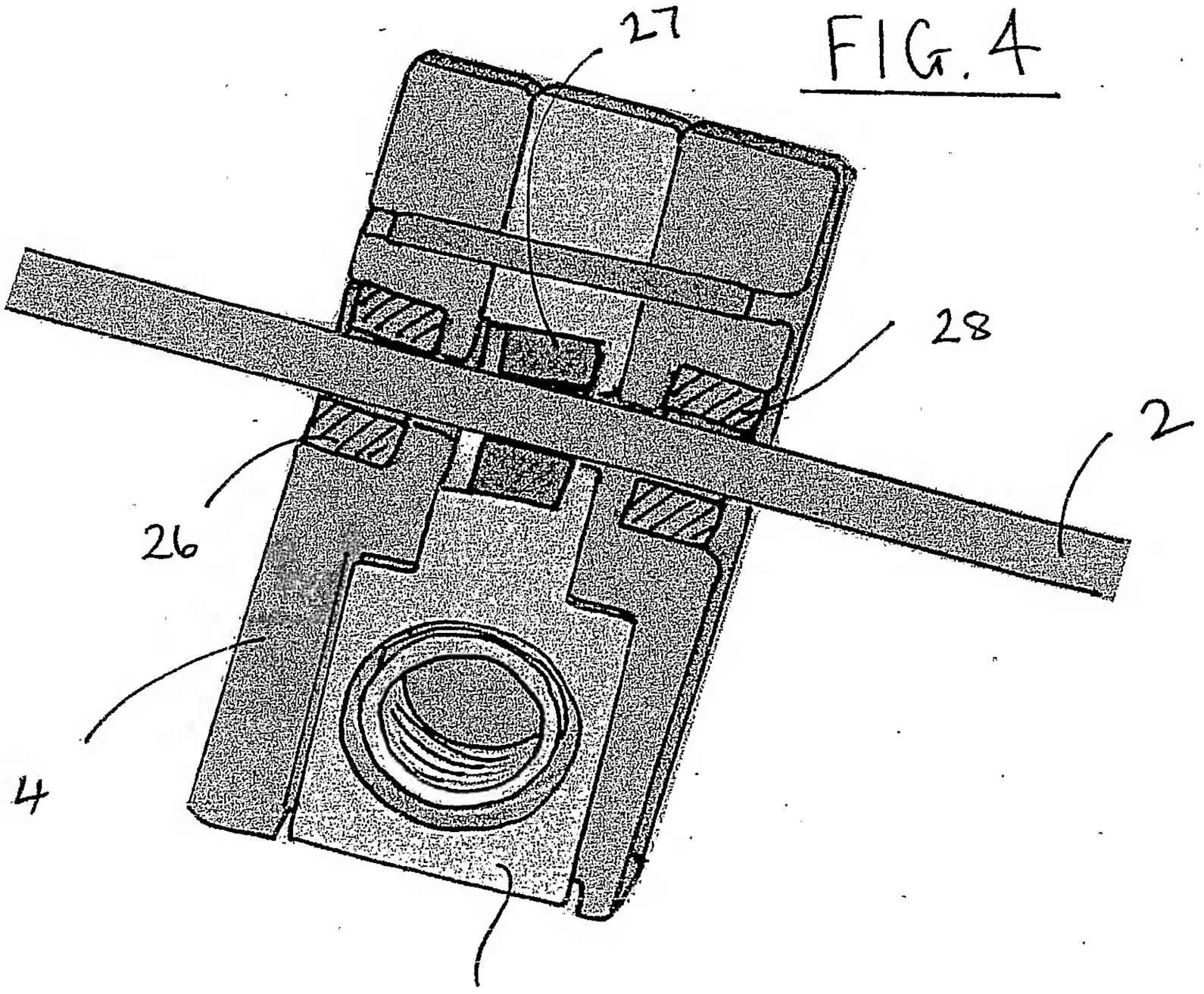

FIG.5

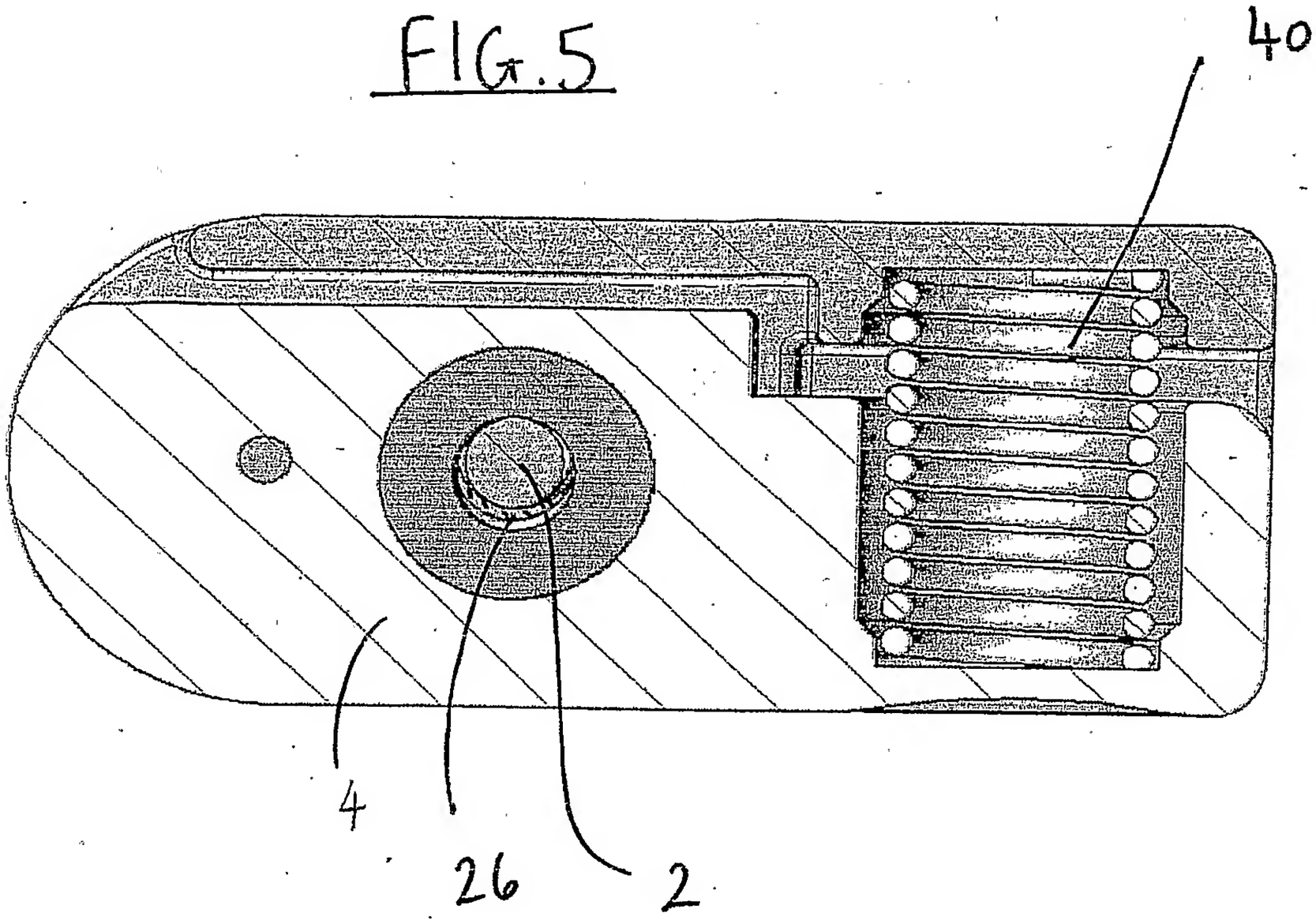

FIG.6